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Guidance for the Reregistration of Pesticide Products Containing Alkyl*Dimethyl Benzyl Ammonium Chloride as the Active Ingredient. Volume 1

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

Alkyl*dimethyl benzyl ammonium chloride
*Alkyl (50% C14, 40% C12, 10% C16)
(069105)

CASE NUMBER 350

CAS 68424-85-1

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers

of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

REGULATORY ASSESSMENT

A. INTRODUCTION

This registration standard describes the regulatory position and rationale of the Environmental Protection Agency ("The Agency") based upon an evaluation of all registered products which contain Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) and all their respective uses.

Future requests for registration of substantially similar products will be covered by this standard. Dissimilar products must be evaluated in order to be registered. If new products are proposed with dissimilar use patterns, formulation type, precautionary statements, etc., the standard will be amended accordingly. After briefly describing the chemical and its uses, this chapter presents the regulatory position and rationale, the criteria for registration, acceptable ranges and limits, and labeling considerations.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met the criteria for unreasonable adverse effects of Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these criteria are candidates for a Special Review, an intensive risk/benefit analysis. The Agency's determination as to whether any criteria have been met and its rationale for any regulatory action are summarized in the regulatory position/rationale section of this standard.

B. DESCRIPTION OF THE CHEMICAL

Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) belongs to a group called "quaternary ammonium compounds. It is registered under numerous trade names and will be hereafter referred to throughout this standard as "ADBAC". A "common name" has not been established by the American National Standards Institute, Inc. (ANSI) or other official organizations concerned with the nomenclature of pesticides. The Chemical Abstract Service Registry Number (CAS) is 68424-85-1 and the Agency's Chemical Code Number is 069105.

The manufacturing-use products (MUP's) of ADBAC, available in two grades (a 50% and 80% solution), is a clear yellow to straw colored liquid with an amine odor. It is soluble in water and alcohols. This ingredient is reported to be stable. The viscosities of the 50% and 80% solutions are 42 cps and 1200 cps, respectively.

ADBAC is effective against a broad spectrum of microorganisms. It is registered as a bactericidal, fungicidal, and algaecidal agent in a variety of indoor and aquatic sites such as cooling towers, oil field recovery systems, swimming pools, animal quarters, household premises, commercial & industrial premises hospital premises, food processing equipment, etc. (see the "EPA Pesticide Index" (which is located in Volume Two) for a description of all uses).

There are thirty registered MUP's products containing ADBAC as a single active ingredient. This ingredient is also registered in combination with other active ingredients in 8 additional MUP's. The multiple active ingredient products include ingredients such as other quaternary ammonium compounds, glycols, phenolics, etc.

C. REGULATORY POSITION AND RATIONALE

Based on a review and evaluation of all available data submitted to EPA and other relevant information on Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}), the Agency has made the following determinations:

1. The available toxicology data adequately define the acute toxicity of ADBAC. However, additional data are being required as outlined in the data tables to assess the subchronic and chronic effects of this compound.

   Rationale: Available data are insufficient to fully assess the toxicity of ADBAC. The Agency is requiring a full battery of subchronic and chronic data to determine the health effects of ADBAC. The Agency is requiring this testing because a number of uses such as: the indoor use, swimming pool use, use in fabrics, fibers and textiles, use in water humidifiers and spraying applications are likely to result in significant human exposure.

Primary acute eye and dermal irritation studies demonstrate severe eye and skin damage (toxicity category I) for the manufacturing-use products. The acute dermal and the oral LD_{50} were >5 grams/kg and 0.43 cc/kg, thus classifying the studies into catagory III and II respectively. An acute inhalation study indicates an LC_{50} at >2.0 mg/kg.

The Agency has two teratogenicity studies on file. The rabbit study showed the NOEL to be >30mg/kg/day. The rat study showed the NOEL to be >50mg/kg/day. The chronic dog study showed the NOEL to be 12.5 mg/kg (LDT)and the LEL to be 25 mg/kg. The effects seen at this dose were moderate congestion and irritation of the small intestine. No gross pathologic lesions were observed.

In addition to the subchronic and chronic studies, a number of special studies are required. The leaching study is required to determine the amount of chemical leached from the treated fabric. Additional studies may be necessary depending on the outcome of the leaching study. The use of the product in swimming pools is likely to result in repeated eye exposure, thus requiring a subchronic eye irritation study. In addition, a light sensitization study is required to determine photosensitivity upon chemical exposure in the presence of light.

2. Data on the environmental fate and exposure of ADBAC are being required as outlined in the data tables.

Rationale: Available data are insufficient to fully assess the environmental fate of ADBAC and the exposure to humans and other nontarget organisms. Thus, data are being required to assess the environmental fate and transport of, and the potential exposure to this chemical. When the additional data are submitted, a full assessment will be made.

Although expected to be minimal, some exposure may occur from use of certain formulations of ADBAC. Dermal and ocular exposure may occur during mixing and loading the emulsifiable concentrates, soluble concentrate/solid, soluble concentrate/ liquid, and flowable concentrate formulations of ADBAC as a result of splashing. Dermal exposure also may occur

from use of the granular, pelleted products, and impregnated material formulations. Dermal, ocular and inhalation exposure may occur during use of the pressurized liquids and ready-to-use formulations. These exposures should be minimized by the use of gloves, respirators and other protective clothing.

3. The Agency is requiring all product labels for the manufacturing use product to require use of rubber gloves and goggles or face shields for the protection of eyes and skin during handling.

   Rationale: As noted above, exposure to MUP products should be minimized by use of protective equipment. Some product labels already recommend the use of rubber gloves and goggles or face shields to protect the eyes and skins during handling. However, this requirement does not exist on all product labeling particularly some of the older registered labels. Since these products have been shown to cause irreversible eye damage and severe skin irritation in laboratory test animals, the Agency is requiring that protective equipment be used during handling of all manufacturing-use products.

4. Currently there are no registered food crop uses; hence, no irrigation crop data are being requested. However a crop irrigation label restriction is required.

   Rationale: Possible residues may occur from discharges of use sites such as cooling towers, paper mills, swimming pools, etc. which may enter waters used for irrigation. The Agency therefore is requiring a crop irrigation label restriction to ensure that residues from use of this chemical do not enter such water systems.

5. Data to assess the effects on wildlife and aquatic organisms are being required as outlined in the data tables. When the additional data are submitted, a full assessment will be made.

Rationale: Available data are insufficient to assess the effects on wildlife and aquatic organisms. Additional data are required to establish the acute toxicity of ADBAC to birds and aquatic invertebrates as well as the chronic toxicity to fish and aquatic invertebrates.

Based upon available data, ADBAC is slightly toxic to bobwhite quail and mallard ducks and moderately to highly toxic to freshwater fish. When used as directed in outdoor use patterns, such as cooling towers, pulp and paper mills and swimming pools, ADBAC is expected to enter the aquatic environment as a domestic/commercial effluent. Hence, data are required and precautionary labeling statements regarding effluent discharge and fish toxicity are being imposed as set forth in section F (Required labeling).

6. Data on the product chemistry (generic) of ADBAC are being required as outlined in the data tables (Table A).

   Rationale: Data are not available to address the generic data requirements for ADBAC. To date, no registrant has removed the reaction solvents (e.g. water and/or ethanol) from the technical material, isolated the chemical and then tested this composition as described in § 63-2 through § 63-13 of the product chemistry guidelines. These tests are required for each manufacturer.

7. Data on the product chemistry (manufacturing-use products are being required as outlined in the data tabeles (Table B).

   Rationale: Available data are insufficient to assess the specific data requirements of the manufacturing-use products, more specifically the manufacturing process, formation of impurities, analysis, certification of limits and analyical methods. Data are required from each of the current manufacturers for each MUP they currently have registered containing the chemical.

   The physical and chemical characteristics for the manufacturing-use products are not being requested at this time since the Agency has adequate representative data.

8. ADBAC is not being classified for Restricted Use.

   Rationale: Available data do not show that any of the risk criteria listed in 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of this chemical specified in this standard to warrant restriction of these uses.

9. Manufacturing-use pesticide products containing ADBAC as an active ingredient may be registered for sale, distribution and reformulation and use, subject to the terms and conditions specified in this standard.

   Rationale: Under FIFRA, the Agency normally does not cancel or withhold registration because data are missing or inadequate (for example, see Section 3(c)(2)(B) and 3(c)(7) of FIFRA). Issuance of this standard provides a mechanism for identifying data needs for registration under the standard and time frames for generating the data. Labeling modifications are also required within a specified time. These data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration of the chemical.

D. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

Manufacturing use products which are subject to this standard, must meet the following conditions along with the others noted in this standard:

1. Contain Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) as an active ingredient,

2. Bear required labeling as set forth in the Required Labeling section of this standard, and

3. Conform to the product composition, acute toxicity limits, and use pattern requirements listed in the Acceptable Ranges and Limits section of this document.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including a commitment to fill data gaps on the schedule required by this Agency. All applicants for registration under this standard must follow the instructions contained in this standard and complete and submit the appropriate forms and information within the time specified.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this standard the manufacturing -use product must contain the active ingredient and each formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider for registration technical grade products and manufacturing-use products, provided the product is supported by toxicity data and the labeling for the product bears appropriate precautionary statements, consistent with the acute toxicity categories under Section 162.10 of 40 CFR.

3. Use Patterns

To be registered under this standard, manufacturing -use products must be labeled for formulation into end-use products. The currently registered use patterns are outlined in the index which is located in Volume Two.

F. REQUIRED LABELING

All manufacturing-use products must bear appropriate labeling as specified in 40 CFR 162.10, in addition to the following specific labeling requirements.

1. Use Pattern Statement

All manufacturing-use products must bear the following statement:

For use by manufacturers only in formulating microbiocides, algaecides, disinfectants, sanitizers & fungicides.

2. Precautionary Statements

a. All manufacturing-use products must bear the following environmental hazard statements:

ENVIRONMENTAL HAZARDS
This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Note: End-use products which employ an effluent will require above statement also.

b. All manufacturing-use products must bear the following front panel precautionary toxicity statements:

KEEP OUT OF REACH OF CHILDREN

DANGER

c. All manufacturing-use products must bear the following toxicity statements:

Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of Practical Treatment
In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

Note to Physician
Probable mucosal damage may contraindicate the use of gastric lavage.

3. Use Directions

a. These products have not been classified as general use pesticides. Therefore the statements "General Classification" or "General Use" must be deleted from all registered labels and will no longer be permitted on any new registrations.

b. All products which employ an effluent will require the following statement:

Do not use water containing residues from use of this product to irrigate crops used for food or feed.

The required statements listed in this standard must appear on the labels of all MUPs released for shipment after December 1, 1986. After the review of the data to be submitted under this standard, the Agency may impose additional label requirements.

G. TOLERANCE REASSESSMENT

There are currently no residue data requirements since there are no registered food or feed uses for this chemical. However, there are end-use products which are registered by this Agency for use as sanitizers and disinfectants in animal quarters, for applications to food processing premises and/or equipment, as a chemical additive to adhesives used in food packaging materials. Although these applications may introduce residues of ADBAC into items of food or feed, they are permitted and are regulated by the Food and Drug Administration (FDA) as indirect food additives and/or drugs and, therefore, may be used under the conditions prescribed by FDA.

Under the Federal Food, Drug and Cosmetic Act (FFDCA), ADBAC is permitted under several sections.

1. Sanitizing solutions for food contact surfaces for solutions not exceeding 200 ppm are permitted under 21 CFR 178.1010(b)(9).

2. Slimicides for use in the manufacture of paper and paperboard that contact food are permitted under 21 CFR 176.300.

3. Adhesives which are used as components of articles intended for use in packaging, transporting or holding food are permitted under 21 CFR 175.105.

4. The Bureau of Veterinary Medicine at FDA, which has jurisdiction over uses such as hand sanitizers, hatching egg sanitizers, udder & flank washes and teat dips, has determined that it has no objections to this chemical at the present time.

If a registrant proposes a food and/or feed use, he will be required to satisfy the data requirements to establish a tolerance. If the tolerance is established, the Agency will amend the standard accordingly.

H. INCIDENTAL FOOD ADDITIVE ASSESSMENT

End-use products containing ADBAC will not be registered under this standard for use as a terminal sanitizing rinse on food contact surfaces in establishments engaged in processing or preparing food for consumption by the general public, unless they are cleared for this use in accordance with the provisions of Section 178.1010 of Title 21 of the Code of Federal Regulations.

Rationale: Antimicrobial agents which are recommended or sold to control the growth of microorganisms of public health concern on inanimate surfaces are defined as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and, therefore, must be registered with

the Environmental Protection Agency (EPA). However, pesticides recommended for this use are also identified as incidental food additives under the Federal Food, Drug, and Cosmetic Act (FFDCA) and, therefore, must comply with the regulations at 21 CFR §178.1010, governing sanitizing solutions, which are administered by the Division of Food and Color Additives of the Food and Drug Administration (FDA).

The Food and Drug Administration exercises authority over establishments which are engaged in the business of processing or preparing food for consumption by the general public, such as restaurants, food processing plants, dairies, soft drink plants, breweries, etc. To ensure that food processed or prepared in such establishments is not contaminated with microorganisms which may be injurious to the public, the FDA requires that food processing equipment, utensils, and food contact surfaces be precleaned and washed to remove gross filth and food particles, rinsed with water to remove traces of detergent, and rinsed with a terminal sanitizing solution.

Such solutions may only contain antimicrobial agents and other chemical ingredients at specified concentrations as approved at Section 178.1010 of 21 CFR; and treated utensils, equipment, and surfaces must be allowed to dry adequately by drainage (air dried) before they are used.

Products which are now being used or recommended as sanitizing solutions to treat food contact surfaces, and which bear label recommendations to follow such treatment with a potable water rinse negate the purpose and intent of the treatment and will no longer be allowed. Furthermore, a potable water rinse may recontaminate the sanitized surfaces with bacteria which may be present in the water, thus introducing a risk to public health. Hence, the use of an antimicrobial at the sanitizing level of activity on food contact surfaces is defined as a terminal sanitizing rinse; and although the EPA has approved antimicrobial labels for this use in the past with a potable water rinse recommendation, such labels will no longer be approved.

I. EFFICACY EVALUATION SUMMARY

No product specific microbiological efficacy data were evaluated for this quaternary ammonium chloride.

Rationale: The only data normally required by the Agency for manufacturing-use products which are to be reformulated into antimicrobials is presumptive evidence of their effectiveness. Since this quaternary ammonium chloride has been widely used as antimicrobials for many years and many studies has demonstrated its efficacy, this presumptive evidence has already been established and no data will be required for MUP's.

Nor will efficacy data be required for products bearing claims for effectiveness against microorganisms of economic or aesthetic significance. Such claims are defined as non-health related and the Agency has waived the submission of product performance data for these uses.

Section 162.18-2(d)(2) of 40 CFR requires that "efficacy data specific to each product that bears a claim to control organisms that may pose a threat to human health, either directly or through transmittal of disease" must be submitted to support the registration of such a product. Each antimicrobial product intended to control microorganisms infectious to man in any area where these microorganisms may present a health hazard falls under the requirement of this section. Microbiological efficacy data are product specific; data for one product can not be used to support registration of another product unless the two products are identical. Even then confirmatory data is required to register a product relying on data developed with another product.

The specific data requirements for end-use products intended to provide health related benefits and the conditions under which the Agency will evaluate previously submitted efficacy data are available from NTIS.

TABLE A
GENERIC DATA REQUIREMENTS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below [3]
§158.120 Product Chemistry						
Product Identity:						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	[x]	[ ]	1	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	[x]	[ ]		6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	[x]	[ ]	1	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	[x]	[ ]	1	6 Months
63-3 - Physical State	TGAI	R	[x]	[ ]	1	6 Months
63-4 - Odor	TGAI	R	[x]	[ ]	1	6 Months
63-5 - Melting Point	TGAI	R	[x]	[ ]	1	6 Months
63-6 - Boiling Point	TGAI	R	[ ]	[x]		

TABLE A
GENERIC DATA REQUIREMENTS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below [3]
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[x]	[ ]	1	6 Months
63-8 - Solubility	TGAI or PAI	R	[x]	[ ]	1,2	6 Months
63-9 - Vapor Pressure	PAI	R	[ ]	[x]		
63-10 - Dissociation constant	PAI	R	[x]	[ ]		6 Months
63-11 - Octanol/water partition coefficient	PAI	R	[x]	[ ]		6 Months
63-12 - pH	TGAI	R	[x]	[ ]	1	6 Months
63-13 - Stability	TGAI	R	[x]	[ ]	1	6 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	CR	[ ]	[x]		

§158.120 Product Chemistry (Continued)

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1. For technical grades of this active ingredient (TGAI), detailed composition data are required on beginning materials. The submitted data should include information from suppliers on impurities present in the beginning materials. The manufacturer is also required to submit for his technical material [after removing the reaction solvent(s)] the preliminary analysis described by § 62-1 and the physical/chemical properties data described in § 63-2 through §63-13. Alternatively, he may furnish for each of the three alkyl dimethyl benzyl ammonium chlorides (without solvents), the physical/chemical property data described by § 63-2 through §63-13.

2. The solubility in quantitative terms at 20° or 25°C is required.

3. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 6 Month Due Date is December 1, 1986.
   - 12 Month Due Date is June 1, 1987.

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	D	NO	_____	YES	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	D	NO	_____	YES	9 Months
161-3 - On soil	TGAI or PAIRA	—	—	_____	NO	
161-4 - In Air	TGAI or PAIRA	—	—	_____	NO	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	—	—	_____	NO	
162-2 - Anaerobic Soil	TGAI or PAIRA	—	—	_____	NO	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	NO	_____	YES	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	NO	_____	YES	27 Months
MOBILITY STUDIES:						
163-1 - Adsorption/Desorption	TGAI or PAIRA	D	NO	_____	YES	12 Months
163-2 - Volatility (Lab)	TEP	—	—	_____	NO	
163-3 - Volatility (Field)	TEP	—	—	_____	NO	

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission[3]
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	—	—	—	NO	
164-2 - Aquatic (Sediment)	TEP	D	NO	—	YES	27 Months
164-3 - Forestry	TEP	—	—	—	NO	
164-4 Combination and Tank Mixes						N/A
164-5 - Soil, Long-term	TEP	—	—	—	NO	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	—	—	—	NO	
165-2 - Rotational Crops (Field)	TEP	—	—	—	NO	
165-3 - Irrigated Crops	TEP	—	—	—	NO	
165-4 - In Fish	TGAI or PAIRA	D	NO	—	YES	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	Conditional[4]	NO	—	Conditional[4]	12 Months
Subpart K Re-entry	TEP	—	—	—	NO	

TABLE A
GENERIC DATA REQUIREMENTS

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§158.130 Environmental Fate - Continued

1. Composition: TGAI = Technical grade of the active ingredient; NOTE: the test substance will be the 80% grade technical TEP = Typical end-use product. PAIRA = Pure active ingredient, radiolabelled;
2. The use pattern is coded as follows: D=Aquatic, Non-Food
3. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 9 Month Due Date is March 1, 1987.
   - 12 Month Due Date is June 1, 1987.
   - 27 Month Due Date is September 1, 1988.
4. Required if fish accumulation data show residues

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Dat Submission [3]
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	D,H,I	YES	00091392	NO	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	D,H,I	YES	00119432	NO	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	D,H,I	YES	00091136	NO	
81-7 - Delayed Neurotoxicity - Hen	TGAI	D,H,I	NO		NO	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding : - Rodent, and	TGAI	D,H,I	NO		YES[4]	15 Months
- Non-rodent (Dog)			YES	00081372,00081374	NO	
82-2 - 21-Day Dermal - Rabbit	TGAI	D,H,I	NO		NO[5]	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	D,H,I	NO		YES	15 Months
82-4 - 90-Day Inhalation: - Rat	TGAI	D,H,I	NO		YES	15 Months
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	D,H,I	NO		NO	
-Mammal						

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:	TGAI	D,H,I			YES[6]	50 Months
- Rodent, and			NO			
- Non-rodent (Dog)			YES	00081372,00081374	NO	
83-2 - Oncogenicity - 2 species:	TGAI	D,H,I	NO		YES	50 Months
- Rat (preferred), and						50 Months
- Mouse (preferred)						
83-3 - Teratogenicity - 2 species:	TGAI	D,H,I	YES	00067661	NO	
- Rat				00055209	NO	
- Rabbit						
83-4 - Reproduction - Rat 2-generation	TGAI	D,H,I	NO		YES	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	D,H,I	NO		YES[7]	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	D,H,I	NO		YES	12 Months
84-4 - Other Genotoxic Effects	TGAI	D,H,I	NO		YES	12 Months

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Dat Submission [3]
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	TGAI	D,H,I	NO		YES	24 Months
86-1 - Domestic Animal Safety	TGAI	D,H,I	NO		NO	
OTHER TESTING						
Eye Irritation (Subchronic)	TGAI	D,H,I	NO		YES	12 Months
Leaching	TGAI	D,H,I	NO		YES[9]	9 Months
81-6 Sensitization	TGAI	D,H,I	NO		YES[8]	9 Months

TABLE A
GENERIC DATA REQUIREMENTS

§158.135 Toxicology - Continued

1. Composition: TGAI = Technical grade of the active ingredient. NOTE: the test substance will be the 80% grade technical
2. The use patterns are coded as follows: D=Aquatic, Non-Food; H=Domestic Outdoor; I=Indoor.
3. Data must be submitted within the indicated time frame, based on the date of the Guidance Document....
   - 9 Month Due Date is March 1, 1987.
   - 12 Month Due Date is June 1, 1987.
   - 15 Month Due Date is September 1, 1987.
   - 24 Month Due Date is June 1, 1988.
   - 39 Month Due Date is September 1, 1989.
   - 50 Month Due Date is August 1, 1990.

4. A 90-day rodent feeding study is required
5. 90-day dermal study will satisfy this requirement
6. A chronic rodent toxicity is required
7. Ames test is not appropriate for a bacteriostatic agent. Therefore, a gene mutation test should be conducted in mammalian cells
8. Light sensitization study is required for swimming pool use chemicals
9. Leaching study is required for chemicals whose pesticidal use (textiles, fabrics, fibers) is likely to result in repeated human skin contact.

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[6]	Use Pattern[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [7]
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Acute Avian Oral Toxicity	TGAI	D,(H,I)[2]	NO		YES 9 Months
71-2 - Avian Subacute Dietary Toxicity	TGAI	D,(H,I)[2,3]			
- Upland Game Bird, and			YES	00119707 00104009	NO
- Waterfowl			YES	00119707 00104008	NO
71-4 - Avian Reproduction	TGAI		NO		NO
- Upland Game Bird, and					
- Waterfowl					
71-5 - Simulated Field Testing	TEP		NO		NO
- Mammals, and					
- Birds					
- Actual Field Testing	TEP		NO		NO
- Mammals, and					
- Birds					

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No.
4. Title and Subtitle: Guidance for the Reregistration of Pesticide Products Containing Alkyl*dimethyl benzyl ammonium chloride as the Active Ingredient (VOL 1)			5. Report Date: Issued 9/85 6.
7. Author(s): EPA, Office of Pesticide Programs, Registration Div.			8. Performing Organization Rept. No.: 540/RS-86-103
9. Performing Organization Name and Address: US Environmental Protection Agency Office of Pesticide Programs Registration Division TS-767C 401 M Street, SW Washington, D. C. 20460			10. Project/Task/Work Unit No. 11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address: Same as #9			13. Type of Report & Period Covered 14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

*Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16})

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
Publicly Available	unclassified	78
	20. Security Class (This Page) unclassified	22. Price

(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77) (Formerly NTIS-35) Department of Commerce

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[6]	Use Pattern[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission[7]
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Coldwater Fish Species, and	TGAI	D[4],(H,I)[2],[3]	NO	00058836, 00064897	YES	9 Months
- Warmwater Fish Species			NO	00093322, 00119694, 00058836	YES	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	D,(H,I)[2]	NO		YES	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	D				
- Fish			NO		YES	12 Months
- Mollusk			NO		YES	12 Months
- Shrimp			NO		YES	12 Months
72-4 - Fish Early Life Stage, and	TGAI	D[5]	NO		YES	15 Months
- Aquatic Invertebrate Life-Cycle		D	NO		YES	15 Months

TABLE A
GENERIC DATA REQUIREMENTS

Data Requirement	Composition[6]	Use Pattern[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [7]
§158.145 Wildlife and Aquatic Organisms - Continued					
72-5 - Fish - Life-Cycle	TGAI		NO		NO
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product		NO		NO
- Crustacean					
- Fish					
- Insect Nymph					
- Mollusk					
72-7 - Simulated Field Testing - Aquatic Organisms	TEP		NO		NO
- Actual Field Testing -Aquatic Organisms					

TABLE A
GENERIC DATA REQUIREMENTS

§158.145 Wildlife and Aquatic Organisms - Continued.

1. The use patterns are coded as follows: D=Aquatic, Non-Food; H=Domestic Outdoor; I=Indoor.

2. For manufacturing use product

3. Only one species required

4. Flow-through tesing is required. Available data indicate disspation of compound from open containers. Also, environmental exposure may be on a recurrent basis as an effluent.

5. The most sensitive species should be tested (bluegill sunfish)

6. Composition: TGAI = Technical grade of the active ingredient.NOTE: the test substance will be the 80% grade technical TEP = Typical end-use product; PAI = pure active ingredient;

7. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 9 Month Due Date is March 1, 1987.
   - 12 Month Due Date is June 1, 1987.
   - 15 Month Due Date is September 1, 1987.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Guideline Citation and Name of Test	Test[4] Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below [5]
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	[ ]	[x]		
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	[x]	[ ]	1	6 Months
61-3 - Discussion of Formation of Impurities	MP	R	[x]	[ ]	2	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	[x]	[ ]	2	12 Months
62-2 - Certification of Limits	MP	R	[x]	[ ]		12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	[x]	[ ]	2,3	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	[ ]	[x]		
63-3 - Physical State	MP	R	[ ]	[x]		
63-4 - Odor	MP	R	[ ]	[x]		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Guideline Citation and Name of Test	Test[4] Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below [5]
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	[ ]	[x]		
63-12 - pH	MP	CR	[ ]	[x]		
63-14 - Oxidizing or Reducing Action	MP	CR	[ ]	[x]		
63-15 - Flammability	MP	CR	[ ]	[x]		
63-16 - Explodability	MP	R	[ ]	[x]		
63-17 - Storage Stability	MP	R	[ ]	[x]		
63-18 - Viscosity	MP	CR	[ ]	[x]		
63-19 - Miscibility	MP	CR	[ ]	[x]		
63-20 - Corrosion Characteristics	MP	R	[ ]	[x]		
Other Requirements:						
64- 1 - Submittal of samples	MP	CR	[ ]	[x]		

§158.120 Product Chemistry (Continued)

1. Detailed composition data are required on beginning materials; the submitted data should include information from suppliers on impurities present in beginning materials.

2. The potential for highly toxic impurities, eg. nitrosamines, their analyses and methodology needs to be addressed.

3. Officical AOAC methodology is available for assaying registered products for the active ingredients. However, depending upon the potential for highly toxic impurities, as indicated in footnote 2, additional analytical methodology may be required.

4. MP = Manufacturing-use Product; NOTE: the test substance will be either the 50% or 80% or both depending upon type of product the manufacturer has registered. R = Required; CR = Conditionally Required

5. Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
   - 6 Month Due Date is December 1, 1986.
   - 12 Month Due Date is June 1, 1987.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Five copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 (enclosed) for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Five copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 (enclosed) for latest requirements.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing Alkyl*dimethyl benzyl ammonium chloride *Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Applications and other required information should be submitted to the following address:

John H. Lee PM 31
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703)-557-3675

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Standard For
Alkyl (50% C14; 40% C12; 10% C16) Dimethyl Benzyl Ammonium Chloride

MRID Citation

00055209 Knickerbocker, M.J.; Stevens, K.R. (1977) Teratologic Evaluation of BTC-8358 in Rats: Laboratory No. 5433-b. (Unpublished study received Oct 14, 1977 under 1839-32; prepared by Food and Drug Research Laboratories, Inc., submitted by Onyx Chemical Co., Jersey City, N.J.; CDL:232094-A)

00058836 Krize, J.; Gilman, M.R. (1974) Report: The Toxic Effects of Lonza Barquat MB-80 in Bluegill Sunfish and Rainbow Trout: Laboratory No. ED-0212. (Unpublished study received on unknown date under 6836-14; prepared by Cannon Laboratories, Inc., submitted by Lonza, Inc., Fair Lawn, N.J.; CDL:224585-A)

00064897 Hogan, J.W. (1969) 32. Toxicity of Hyamine 3500 to fish. Pages 3-9, In Investigations in Fish Control. Washington, D.C.: U.S. Fish and Wildlife Service. (Available from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; published study; CDL:226905-J)

00067661 Piccirillo, V.J. (1978) Final Report: Teratogenic Evaluation in Rabbits: Project No. 417-364. (Unpublished study received Aug 1, 1978 under 707-63; prepared by Hazleton Laboratories America, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 234564-A)

00081372 Coulston, F.; Drobeck, H.; Mielens, Z. (1961) Toxicology of benzalkonium chloride given orally in milk or water to rats and dogs. Toxicology and Applied Pharmacology 3(5):584-594.

00081374 Alfredson, B; Stiefel, J.; Thorp, F. (1951) Toxicity studies on alkyldimethylbenzylammonium chloride in rats and in dogs. Journal of the American Pharmaceutical Association XI(6):263-267.

00091136 Taylor, R.E. (1973) Report of Analysis: Hyamine 3500-80%: Laboratory No. 8380. (Unpublished study received Feb 16, 1978 under 707-63; prepared by Harris Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:232857-L)

00091392 Wallace, J.M., comp. (1975) Toxicity Studies: Barquat MB-80. (Unpublished study received Jul 17, 1975 under 6836-14; prepared by Bio-Toxicology Laboratories, Inc., submitted by Lonza, Inc., Fair Lawn, N.J.; CDL:140112-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Standard For
Alkyl (50% C14; 40% C12; 10% C16) Dimethyl Benzyl Ammonium Chloride

MRID Citation

00093322 Binns, R.; Clark, G.C. (1969) The Acute Toxicity To Fish of Hyamine 3500: 2938/69/364. (Unpublished study received May 24, 1978 under 707-146; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 234002-N)

00104008 Shapiro, R. (1974) Evaluation of Subacute Toxicity of Di-methyl Benzyl Amonium Chloride to Mallard Ducks: Report No. 519. (Unpublished study received Jul 23, 1974 under 3876-102; prepared by Nutrition International, Inc., submitted by Betz Laboratories, Inc., Trevose, PA; CDL:131506-A)

00104009 Shapiro, R. (1974) Evaluation of Subacute Toxicity of Di-methyl Benzyl Ammonium Chloride to Bob White Quail: Report No. 536. (Unpublished study received Jul 23, 1974 under 3876-102; prepared by Nutrition International, Inc., submitted by Betz Laboratories, Inc., Trevose, PA; CDL:131506-B)

00119432 Levenstein, I. (1977) Dermal LD50: [Barquat MB-80--Rabbits]: Assay No. 73130. (Unpublished study received Apr 5, 1977 under 6836-2; prepared by Leberco Laboratories, submitted by Lonza, Inc., Fair Lawn, NJ; CDL:232245-A)

00119694 Sleight, B. (1971) Acute Toxicity of Hyamine 3500 to Bluegill, (Lepomis macrochirus). (Unpublished study received Nov 14, 1972 under 707-63; prepared by Bionomics, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:120307-H)

00119707 Terrell, Y.; Gilman, M. (1974) Eight Day Dietary LC50 Study of Barquat MB-80 on Bobwhite Quail and Mallard Ducks: Laboratory No. E-9644. (Unpublished study received Oct 21, 1974 under 6836-2; prepared by Cannon Laboratories, Inc., submitted by Lonza, Inc., Fair Lawn, NJ; CDL:131705-A)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Appendix III-1 (continued)

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX IV -1

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for

whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to

other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22–25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the

basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 20° F. if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(*2*) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

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(continued)

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Appendix IV-4
(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

Appendix IV-4
(continued)

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene